

**TRANSMITTAL AND NOTICE OF APPROVAL OF
STATE PLAN MATERIAL**

FOR: HEALTH CARE FINANCING ADMINISTRATION

RECEIVED

TO: REGIONAL ADMINISTRATOR
HEALTH CARE FINANCING ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

MAR 15 2004

1. TRANSMITTAL NUMBER:

004-02

2. STATE
Idaho

3. PROGRAM IDENTIFICATION: TITLE XIX OF THE
SOCIAL SECURITY ACT (MEDICAID)

4. PROPOSED EFFECTIVE DATE
January 1, 2004

5. TYPE OF PLAN MATERIAL (Check One):

☐ NEW STATE PLAN

☐ AMENDMENT TO BE CONSIDERED AS NEW PLAN

☒ AMENDMENT

COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT (Separate Transmittal for each amendment)

6. FEDERAL STATUTE/REGULATION CITATION:

Section 1927 of S.S.A. (42 USC 1396r-8)

7. FEDERAL BUDGET IMPACT:

a. FFY 2004 (\$ 2,371,536.00)
b. FFY 2005 (\$ 5,454,532.00)

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:

Attachment 4.19-B Page 22
Supplemental Rebate Agreement
Attachments A & B
Merck Agreement

9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION
OR ATTACHMENT (If Applicable):

Attachment 4.19-B page 22
Supplemental Rebate Agreement
Attachment A & B
Merck Agreement

10. SUBJECT OF AMENDMENT:

Supplemental Rebate Agreement

11. GOVERNOR'S REVIEW (Check One):

☒ GOVERNOR'S OFFICE REPORTED NO COMMENT

☐ OTHER, AS SPECIFIED:

☐ COMMENTS OF GOVERNOR'S OFFICE ENCLOSED

☐ NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL

12. SIGNATURE OF STATE AGENCY OFFICIAL:

Karl B. Kurtz

13. TYPED NAME:

KARL B. KURTZ

14. TITLE:

Director

15. DATE SUBMITTED:

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED:

MAR 15 2004

18. DATE APPROVED:

MAY - 7 2004

PLAN APPROVED - ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL:

JAN - 1 2004

20. SIGNATURE OF REGIONAL OFFICIAL:

ISI

21. TYPED NAME:

Karen S. O'Connor

22. TITLE:

Associate Regional Administrator
Division of Medicaid &
Children's Health

23. REMARKS:

3/11
(DATE)

Olympia
(CITY)

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TO: REGIONAL ADMINISTRATOR
HEALTH CARE FINANCING ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

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04-002

2. STATE
IDAHO

3. PROGRAM IDENTIFICATION: TITLE XIX OF THE
SOCIAL SECURITY ACT (MEDICAID)

4. PROPOSED EFFECTIVE DATE
01-01-04

5. TYPE OF PLAN MATERIAL (*Check One*):

☐ NEW STATE PLAN ☐ AMENDMENT TO BE CONSIDERED AS NEW PLAN ☒ AMENDMENT

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☐ NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL

☐ OTHER, AS SPECIFIED:

12. SIGNATURE OF STATE AGENCY OFFICIAL:

13. TYPED NAME:

KARL B. KURTZ

14. TITLE:

Director

15. DATE SUBMITTED:

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED: **FEB 24 2004**

18. DATE APPROVED:

PLAN APPROVED - ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL:

20. SIGNATURE OF REGIONAL OFFICIAL:

21. TYPED NAME:

22. TITLE:

23. REMARKS:

Attachment 4.19-B Program Description - page 22

12. a. Prescription Drugs:
- i. Reimbursement is restricted to those drugs supplied from labelers that are participating in the CMS Medicaid Drug Rebate Program.
 - ii. Reimbursement for all covered drugs shall be limited to the lowest of the following:
 - a) Federal Upper Limit (FUL) as established by CMS, plus the dispensing fee assigned by the Department.
 - b) State Maximum Allowable Cost (SMAC) as established by the Department, plus the assigned dispensing fee.
 - c) Estimated Acquisition cost (EAC)
 - i) Defined as the Average Wholesale Price (AWP) minus 12% plus the assigned dispensing fee.
 - d) The provider's usual and customary charge to the general public.
 - iii. Dispensing Fee:

The dispensing fee shall be one of two types:

 - a) Regular dose fee is \$4.94 per prescription.
 - b) Unit dose fee is \$5.54 per prescription, and is defined as a system of providing individually sealed and appropriate labeled unit dose medication that ensures no more than a 24 hour supply in any client's drug tray at any given time. These trays shall be delivered to the facility at least five days per week.
 - iv. Supplemental Rebate Agreement:

Based on the requirements in Section 1927 of the Act, the state has the following policies for the supplemental drug rebate program for Medicaid recipients:

 - a) The model rebate agreement between the state and drug manufacturers for drugs provided to Medicaid recipients, submitted to CMS on April 23, 2004 and entitled "Supplemental Rebate Agreement" has been authorized by CMS.
 - b) The model rebate agreement between the state and drug manufacturers for drugs provided to Medicaid recipients, submitted to CMS on February 27, 2004 and entitled "Merck Agreement" has been authorized by CMS.
 - c) Supplemental drug rebates received by the state in excess of those required under the national drug rebate agreement will be shared with the Federal government on the same percentage basis as applied under the national drug rebate agreement.
 - d) Manufacturers are allowed to audit utilization rates.

TN No.: 04-002

Supersedes

TN No. 03-002

Approval date MAY - 7 2004

Effective Date:
01-01-04

- e) The unit rebate amount is confidential and cannot be disclosed for purposes other than rebate invoicing and verification, in accordance with 1927 (b) (3) (D).
- f) Payment of a supplemental rebate may not exempt a drug from prior authorization. It is one factor but is secondary to considerations of the safety, effectiveness, and clinical outcomes of the drug in comparison with other therapeutically interchangeable alternative drugs, and the net economic impact of inclusion or exclusion of the drug from prior authorization.
- g) Manufacturers who do not participate in the supplemental rebate program will have their drugs made available to Medicaid beneficiaries through the prior authorization process.

TN NO. 04-002
Supersedes
TN NO. 03-002

Approval Date MAY -7 2004

Effective Date:
01-01-04

SUPPLEMENTAL REBATE AGREEMENT

This Supplemental Rebate Agreement (Agreement) is by and between the **State of Idaho Department of Health and Welfare** (State) and _____ (Provider).

RECITALS

WHEREAS, the State has the authority to enter into agreements with pharmaceutical manufacturers to collect supplemental rebates for the benefit of the State's Medicaid recipients providing such agreements are authorized by the Centers for Medicare and Medicaid Services (CMS); and

WHEREAS, the Provider is willing to provide supplemental rebates to the State based on the actual dispensing of Provider Covered Products under the State's Medicaid program.

NOW THEREFORE, in consideration of the foregoing and of the representations, warranties and covenants set forth below, the parties, intending to be legally bound, agree as follows:

1. **Definitions.** As used herein, the following terms shall have the meanings set forth below:
 - 1.1 **Agreement** means this Supplemental Rebate Agreement, including all documents attached or incorporated by reference.
 - 1.2 **Average Manufacturer Price (AMP)** shall mean, with respect to a covered outpatient drug of a manufacturer for a rebate period, the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts.
 - 1.3 **Average Wholesale Price (AWP)** shall mean the published price of the Covered Product by National Drug Code (NDC) as published by First DataBank on the first day of the calendar quarter that corresponds to the calendar quarter for which the State utilization data for the Covered Product is reported to the Provider.
 - 1.4 **Basic Rebate** shall mean, with respect to the Covered Product, the quarterly payment by the Provider pursuant to the Provider's Medicaid Drug Rebate Agreement made in accordance with Section 1927(c)(1) or Section 1927(c)(3) of the Social Security Act (42 U.S.C. 1396r-8(c)(1) and 42 U.S.C. 1396r-8 (c)(3)).
 - 1.5 **Best Price** shall mean the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity with the exception of those exceptions stated at Section 1927 (c)(1)(C).
 - 1.6 **CMS** shall mean the Center for Medicare and Medicaid Services (formerly known as the Health Care Financing Administration) of the U.S. Department of Health and Human Services (HHS), or any successor or renamed agency carrying out the functions and duties heretofore carried out by such office.
 - 1.7 **Competitive Product** shall mean a pharmaceutical product that is therapeutically interchangeable to one or more Covered Products of Provider.
 - 1.8 **Covered Product** shall mean a pharmaceutical product identified in Attachment A of this Agreement.

- 1.9 **CPI Rebate** means, with respect to the Covered Product, the quarterly payment by the Provider pursuant to the Provider's Medicaid Drug Rebate Agreement, made in accordance with Section 1927(c)(2) of the Social Security Act (42 U.S.C. § 1396r-8(c)(2)).
- 1.10 **IDAPA** means the Idaho Administrative Procedures Act. All references in this Agreement to IDAPA chapters or sections shall include any successor, amended, or replacement rule.
- 1.11 **Ingredient Reimbursement Basis** shall mean the formula used by State to reimburse Pharmacy providers for branded pharmaceuticals.
- 1.12 **Maximum Allowable Cost (MAC)** shall mean the lowest reimbursement rate established by the State for Covered Product.
- 1.13 **Medicaid Drug Rebate Agreement** shall mean the agreement in place between the Provider and the Secretary of Health and Human Services, pursuant to Section 4401 of the Omnibus Budget Reconciliation Act of 1990 (Public Law 101-508). CMS is the agency within HHS having the delegated authority to operate the Medicaid program.
- 1.14 **Medicaid Recipient** shall mean any person enrolled in the State Medicaid Program and eligible to receive prescription drug benefits under a fee for service arrangement.
- 1.15 **Net Cost** shall mean the prescription drug ingredient reimbursement calculated as provided in IDAPA 16.03.09.817.04 minus the sum of all rebates paid by the Provider to the State for the Covered Product for the calendar quarter. In the event of any change to the calculation used by the State to determine drug ingredient reimbursement paid by the State to Pharmacy providers, the applicable terms of this Agreement shall be amended to reflect such change.
- 1.16 **Pharmacy** shall mean a facility licensed to dispense legend drugs and enrolled as a State Medicaid provider.
- 1.17 **Prior Approval Process** shall mean a process by which the State Medicaid Program approves prior to dispensing various pharmaceutical products for the purpose of guiding the prescribing, dispensing and acquisition of pharmaceutical products covered by the State Medicaid Program.
- 1.18 **State Medicaid Program** shall mean the joint federal and state medical assistance program as established and defined pursuant to Title 42 U.S.C. 1396, et seq., that provides reimbursement for or coverage of prescription drug products to Medicaid Recipients.
- 1.19 **State Supplemental Rebate** shall mean an amount paid on a calendar quarter basis by the Provider to the State for utilization under State's fee for service Medicaid program pursuant to the Rebate Formula in Attachment B of this Agreement.
- 1.20 **Unit** means drug unit in the lowest identifiable amount (e.g., tablet or capsule or solid dosage forms, milliliter for liquid forms, gram for ointment or creams).
- 1.21 **USC** means the United States Code. All references in this agreement to USC chapters or sections shall include any successor, amended, or replacement statute.

2. **State Obligations**

- 2.1 **Status Under Prior Approval Process.** To be eligible for the Supplemental Rebates specified in Attachment B, State shall grant Covered Product the status under the Prior Approval Process described in Attachment B, it being agreed that utilization shall be eligible for the State Supplemental Rebate only in quarters in which Covered Product holds the status under the Prior Approval Process described in Attachment B.
- 2.2 **Prior Approval Process Status Publication.** State shall communicate the status of Covered Product to State Medicaid Program providers through the standard notification process.
- 2.3 **Invoicing.** State shall invoice Provider for State Supplemental Rebates separately from CMS Rebates using the format set forth by CMS (Reconciliation of State Invoice format). State shall submit the State Supplemental Rebate invoice to the Provider within sixty (60) days after the end of each calendar quarter in which the Covered Product subject to such State Supplemental Rebate was paid for by State. Any amended invoice shall be submitted by State within fifteen (15) months after the end of the calendar quarter in which Covered Product was paid for by State.
- 2.4 **Patient Information.** State, its agents, employees and contractors shall not provide to the Provider any patient identifiable information or protected health information (PHI) or any other information prohibited or regulated by laws or regulations governing confidentiality of medical or other information.
- 2.5 **Approval of Generic Equivalent.** If during the duration of this Agreement a generic equivalent of any Competitive Product should become available, State will allow Covered Product to retain the status set forth in Attachment B so long as the net cost to the State, as defined in Attachment B, is not more than the lowest reimbursement cost as established by IDAPA 16.03.09.817.04 for a generic equivalent.

3. **Provider Obligations**

- 3.1 **State Supplemental Rebate Payment.** Provider agrees to provide a State Supplemental Rebate for each of its Covered Products that is paid for by the State and dispensed to Medicaid Recipients by Pharmacies for each calendar quarter that Covered Products retain the status under the Prior Approval Process set forth in Attachment B. Provider shall pay to State the State Supplemental Rebate amount in accordance with the formula set forth in Attachment B. State shall remit the appropriate share of the State Supplemental Rebate payments made under the Agreement to CMS as required under its approved state plan. Nothing in this Agreement shall be construed to relieve the Provider from its obligation to pay Basic Rebates to State pursuant to the Medicaid Drug Rebate Agreement.
- 3.2 **Payment Timeframe.** Provider shall pay to State the State Supplemental Rebate amount to which State is entitled in accordance with the formula set forth in Attachment B, within thirty-eight (38) days of Provider's receipt of the State Supplemental Rebate invoice pursuant to Section 2.3.
- 3.3 **Incomplete Submission.** Provider shall have no obligation to pay State Supplemental Rebate amounts for claims that are not submitted as part of an invoice in accordance with Section 2.3 of this Agreement. Provider shall notify State or its designee of any incomplete submission within thirty-eight (38) days after Provider's receipt of such submission pursuant to Section 2.3.

- 3.4 **Over/Underpayment.** If either party discovers an error in the payment of State Supplemental Rebates, it shall notify the other of such error. The parties shall attempt to reconcile all differences through discussion and negotiation; if that attempt fails, the parties will resolve their dispute in accordance with generally accepted applicable procedures followed by State or CMS in disputes concerning Medicaid Drug Rebates. Any overpayment shall be deducted from subsequent State Supplemental Rebates payable under this Agreement. In the event that no subsequent State Supplemental Rebates are payable, State will refund any such overpayment to Provider within thirty (30) days of the parties' acknowledgement of the overpayment. Provider will remit any underpayment to State within thirty (30) days of the parties' acknowledgement of such underpayment.
- 3.5 **Discretion to Market.** Nothing in this Agreement shall be construed to prohibit the Provider from discontinuing production, marketing or distribution of any Covered Product or from transferring or licensing any Covered Product to a third party. It is understood that the Provider is liable for the payment of State Supplemental Rebates only for Covered Products (as identified by the 11-digit NDC code) distributed (directly or through the wholesale channel) to retail Pharmacies and dispensed to Medicaid Recipients. If the Provider elects to discontinue production, marketing or distribution of any Covered Product or to transfer or license any Covered Product to a third party, the Provider shall make every reasonable effort to notify the State prior to such actions.
4. **Term and Termination**
- 4.1 **Effective Date.** This agreement shall be effective as of _____, and shall continue in force through _____, unless it is terminated sooner pursuant to the following:
- a) **Breach.** If either party commits a material breach of this agreement, the non-breaching party shall deliver written notice mailed by certified mail, return receipt requested, of the alleged breach to the breaching party, with an opportunity for the breaching party to cure the breach during the thirty (30) day period following the delivery. Failure to cure shall give the non-breaching party the right to cancel this agreement at the end of the thirty (30) day period. The non-breaching party shall give the breaching party final written notice of the cancellation of this agreement.
- b) **Without Cause.** Either party may terminate this Agreement without cause as of the end of any calendar quarter by giving the other party sixty (60) days prior written notice.
- 4.2 **Accrued Obligations/Remedies.** The expiration or termination of this Agreement shall not affect any rights or obligations of the parties that have accrued prior to the effective date of such termination. The fact that either party exercises any right of termination it may have under this Agreement shall not prevent such party from pursuing any other remedy it may be entitled to in law or equity. Any remedy provided herein shall not be deemed an exclusive remedy unless expressly provided for as such.
- 4.3 **Execution, Amendment, and Waiver.** This Agreement shall be binding only upon signature by both parties. This Agreement, or any provision, may be altered, amended, or waived by a written amendment executed by both parties as authorized by CMS.

5. **Miscellaneous**

- 5.1 **Record Keeping and Audit.** During the term of this Agreement and for a period of five (5) years thereafter, both parties to the Agreement shall use reasonable efforts at all times to ensure that they maintain accurate books, files and records relevant to this Agreement. At Provider's written request, State shall make such information available for inspection by Provider representatives or its designated auditors during regular business hours. Upon written request, each party shall otherwise have the right to inspect, up to once each year, all such relevant books and records of the other party to verify compliance with the terms of this Agreement.
- 5.2 **Indemnification.** Provider shall be responsible for and shall indemnify and hold State harmless from all claims caused by or arising out of Provider's or any subcontractor's negligent or otherwise wrongful performance, act or omission under the Agreement. Nothing in this provision shall extend Provider's and any subcontractor's indemnification of the State beyond the liability of the Department provided in the Idaho Tort Claim's Act, Idaho Code Section 6-901 *et seq.*, the aggregate of which is limited by Idaho Code Section 6-926. State shall be responsible and shall indemnify and hold Provider harmless from all claims caused by or arising out of the State's negligent or otherwise wrongful performance, act, or omission of any term of the Agreement. Nothing in this provision shall extend the liability of the State beyond that provided in the Idaho Tort Claims Act, Idaho Code Section 6-901 *et seq.*
- 5.3 **Confidentiality.** Except as otherwise may be required to be disclosed by law and in accordance with the Medicaid Drug Rebate Agreement between the Secretary of U.S. Department of Health and Human Services and the drug manufacturers, information disclosed by Provider in connection with this Agreement will not be unnecessarily disclosed by the State. Each party shall maintain the confidentiality of all the terms and conditions of this Agreement throughout the term hereof and for a period of three (3) years thereafter.
- 5.4 **Notices.** Any notice required or permitted to be given by either party to the other shall be given in person or sent by first class mail or express delivery, addressed to the other party at the address set forth below.

State Mailing Address:

Laura Windham, Contracts Supervisor
Idaho Dept. of Health and Welfare
Division of Medicaid
Bureau of State Operations
P.O. Box 83720
Boise, ID 83720-0036

Provider Mailing Address:

- 5.5 **Force Majeure.** Noncompliance with any obligations hereunder due to force majeure, such as acts of God, laws or regulations of any government, war, civil commotion, destruction of production facilities and materials, fire, earthquake or storm, labor disturbances, shortage of materials, failure of public utilities or common carriers, and any other causes beyond the reasonable control of the parties, shall not constitute breach of contract.

- 5.6 **Assignment.** Neither party shall have the right to assign this Agreement to a third party without the prior written consent of the other party, which consent shall not be unreasonably withheld. Any permitted assignee shall assume all obligations of its assignor under this Agreement. No assignment shall relieve any party of responsibility for the performance of any obligations that have accrued prior to such assignment.
- 5.7 **No Waiver of Rights.** The failure of either party to insist upon the strict observation or performance of any provision of this Agreement or to exercise any right or remedy shall not impair or waive any such right or remedy in the future. Every right and remedy given by this Agreement to the parties may be exercised from time to time as often as appropriate.
- 5.8 **Entire Agreement.** This Agreement contains the entire agreement and understanding of the parties. This Agreement (including Attachments) may not be amended or modified except upon the written agreement of both parties as authorized by CMS.
- 5.9 **Governing Law.** This Agreement shall be governed by the laws of the State of Idaho. In the event of a lawsuit involving this Agreement, venue shall be proper only in Ada County, Idaho.
- 5.10 **Effect of Future Laws or Interpretations of Law.** In the event of the enactment, promulgation, rescission, modification or interpretation of any law or regulation after the date hereof which would
- (a) materially adversely affect the manner in which either party is obligated to perform under this Agreement,
 - (b) adversely affect for either party the net prices or State Supplemental Rebates or other terms applicable under this Agreement, or
 - (c) have the effect of requiring the net prices or State Supplemental Rebates or other terms applicable under this Agreement to be extended or offered to any third party,
- Each party shall have the right to enter into good faith negotiation with the other in order to seek to agree on reasonable terms for maintaining the intent of the Agreement affected by such enactment, promulgation, etc. Agreement on any such terms shall be in the sole discretion of each party. If the parties do not agree within thirty (30) days of a party's written request for negotiations, either party may terminate this Agreement with respect to the affected Covered Products upon expiration of the thirty (30) day period, with immediate effect.
- 5.11 **Compliance with Law.** In connection with its respective obligations under this Agreement, each party shall comply with all applicable federal, state and local laws and regulations, including without limitation any disclosure or consent requirements.
- 5.12 **Authority.** State and Provider each represent and warrant to the other that the person signing below has all requisite legal power and authority to execute this Agreement on behalf of each party and each party shall thereby be bound.
- 5.13 **Best Price Contingency.** The effectiveness of this Agreement shall be contingent on Provider's Best Price and AMP not being affected by State Supplemental Rebates.

5.14 **CMS Approval Contingency.** The effectiveness of this Agreement shall be contingent on receipt by State of CMS approval of the state plan amendment which authorized the form of this Agreement.

IN WITNESS WHEREOF, this Agreement has been executed by the parties set forth below:

State of Idaho
Department of Health and Welfare
Division of Medicaid

By: _____ **Date** _____
David A. Rogers
Administrator

By: _____ **Date** _____

